REMARKS/ARGUMENTS

Review and reconsideration of the Office Action of June 17, 2003, is respectfully requested in view of the above amendments and the following remarks.

Claims 3, 4 and 6-10 are pending and presented for the examination.

Applicants are submitting herewith a Declaration Under 37 C.F.R. §1.132 including comparative examples between the method of the present invention and the closest example of the closest prior art cited by the Examiner (method of Example I of Pelzer et al. (Pelzer)), in order to demonstrate the unexpected improvement of a process that produces a phenylene-bis-benzimidazole-tetrasulfonic acid disodium salt substantially ***free of by-products that would cause discoloration***. Applicants respectfully request the Examiner to consider the attached Declaration and the accompanying photograph (Attachment A).

As can be seen from the results of the tests as described in both the Declaration and as depicted in the photograph (Attachment A), the phenylene-bis-benzimidazole-tetrasulfonic acid disodium salt of the present invention shows a **remarkable** reduction in the presence of discoloring by-products as compared to the phenylene-bis-benzimidazole-tetrasulfonic acid disodium salt of Pelzer, when incorporated into a cosmetic formulation.

Comparative experiments were conducted to demonstrate that:

-the method of the present invention produces a composition that is free of discoloring byproducts (see Attachment A, bottle

on the right, showing an absence of color). In contrast, the method of Pelzer produces a composition that is colored (see Attachment A, bottle on the left, showing a pink color);

-the process of the present invention produces a composition that is free of discoloring byproducts despite the fact that the process actually increases the amount of trisufonic impurities. Surprisingly, the process results in a decrease in discoloration. In contrast, the prior art only teaches how to reduce the amount of the trisulfonic acid impurity, but does not reduce discoloring byproducts (compare HR 144 and HR 285);

-in the particular process of the present invention, (1) an extension in reaction time and (2) an increase in reaction temperature results in an increase in discoloring impurities (due to an increase in side reactions, condensations, polymerizations, decompositions, or other subsequent reactions of the product, see HR 144-2). This shows that only by using the particular time, temperature and processes of the present invention can a product be obtained that is free of discoloring impurities;

-when the extended time and increased temperature of the present invention was used in conjunction with the process of the prior art, the process of the prior art did not lead to a colorless product (see HR 144-2). Again, this shows that only by using the particular time, temperature and processes of the

present invention can a product be obtained that is free of discoloring impurities; and

-when the process of the present invention was used in conjunction with the shorter reaction time of the prior art, the resulting product was still discolored (see HR 144-3).

Office Action

Turning now to the Office Action in greater detail, the paragraphing of the Examiner is adopted.

Paragraph 1 (Continued Prosecution Application)

The Examiner indicated that the request filed on April 1, 2003 for a CPA under 37 CFR 1.53(d) based on parent Application No. 09/995,328 is acceptable, and a CPA has been established.

Paragraphs 2-5 (Status of Application)

The Examiner acknowledges the amendment filed on March 12, 2003 and new claim 10.

Claims 3, 4 and 6-10 are pending and presented for the examination.

Paragraphs 6-7 (Claim Objections)

The Examiner objects to Claims 3, 4 and 6-10 for various informalities. Applicants appreciate the Examiner's helpful comments, and Applicants have re-formatted the text to remove the extra spaces in Claim 3 and have amended Claims 4, 6-10, per

the Examiner's suggestion.

Entry is respectfully requested. Care has been taken to ensure that no new matter is added. Accordingly, withdrawal of the rejections is respectfully requested.

Paragraph 8 (Obviousness Rejection)

The Examiner rejects all claims as obvious over Pelzer, in view of Wang et al. (Wang) and further in view of Heywang et al. (Heywang).

The position of the Examiner can be found on pages 2-6 of the Office Action.

Applicants respectfully traverse the rejection in view of the evidence contained in the attached Declaration, as discussed below in detail, and in view of the claims.

Paragraph 9 (Examiner's Response to Applicants' Arguments)

The position of the Examiner, the "Response to Applicants' Arguments in Amendment B", can be found on pages 6-8 of the Office Action.

Paragraph 9a.

The Examiner's position is that Applicants have allegedly recognized another advantage that would flow naturally from the suggestion of the prior art. Applicants respectfully disagree and traverse the rejection.

In order for a *prima facie* case of obviousness to be made, there must be a motivation for one skilled in the art to modify the reference. Pelzer teaches how to reduce impurities. Pelzer's focus on reducing impurities would not lead one skilled in the art to modify the parameters such that an **increase** in impurities would occur. Yet, the impurity level of the present invention is almost double that of Pelzer. (See page 6 of the Declaration where HR 144 (the composition of Pelzer's Example I) has a 1.0% concentration of impurities. Compare with page 11 of the Declaration where HR 285 (the composition of the present invention) has a 1.8% concentration of impurities.)

Surprisingly, the process of the present invention produces a composition that is free of discoloring byproducts despite the fact that the process actually increases the amount of trisufonic impurities. Surprisingly, the process results in a decrease in discoloration, which is the opposite of what one skilled in the art would have expected. (See Tables 2 and 3 on page 5 of the Declaration. Compare the color of HR 144 and HR 285. See also Attachment A. Compare the color of HR 144 on the left and HR 285 on the right.) In contrast, the prior art only teaches how to reduce the amount of the trisulfonic acid impurity, but does not teach how to reduce discoloring byproducts.

Thus, there is no motivation to modify Pelzer and Applicants respectfully submit that a *prima facie* case of obviousness has not been made.

Further, for a *prima facie* case of obviousness to be made, there must also be a showing that the prior art teaches or suggests all of the limitations of the claims. Pelzer does not teach the limitation of Claim 3 that recites a process that produces a phenylene-bis-benzimidazole-tetrasulfonic acid disodium salt substantially ***free of by-products which would cause discoloration***. Therefore, Pelzer does not teach all of the limitations of the present claims. Even the combination of the secondary references, Wang and Heywang, do not teach the reduction of discoloring byproducts. Thus, Applicants respectfully submit that a *prima facie* case of obviousness has not been made.

Finally, even if it were presumed that one wanted to prevent discoloration, it would not be obvious that a process which resulted in an increase in impurities would result in less discoloration.

Paragraph 9b.

It is also the position of the Examiner that there was allegedly no evidence on the record that would lead one of ordinary skill in the art to expect an increase in impurities with extended reaction times. The Examiner points out that the stability of a reaction depends upon a particular process.

In response, Applicants have conducted comparison experiments designed to show that, in the particular process of the present invention, (1) an extension in reaction time and (2)

an increase in reaction temperature results in an increase in discoloring impurities (due to an increase in side reactions, condensations, polymerizations, decompositions, or other subsequent reactions of the product).

As shown in the Declaration, HR 144-2 was produced using the process of Pelzer, but used the increased time and increased temperature of the present invention. As is clearly shown in Tables 2 and 3 of the Declaration, the cosmetic formulation containing HR 144-2 showed the presence of discoloring byproducts of phenylene-bis-benzimidazole-tetrasulfonic acid disodium salt that the present invention (HR 285) overcomes.

The stability of the cosmetic formulation that included HR 144-2 was observed at two different temperatures after 2 weeks and again after 4 weeks. The cosmetic formulation containing HR 144-2 displayed "faintly pink, slightly pink, slightly pink and pink" discoloration properties, respectively. In contrast, the cosmetic formulation containing the product of the present invention, HR 285, remained free of color. Thus, when the extended time and increased temperature of the present invention was used in conjunction with the process of Pelzer, the process of Pelzer did not lead to phenylene-bis-benzimidazole-tetrasulfonic acid disodium salt that is free of discoloring byproducts. Simply changing the times and temperatures of Pelzer to match the parameters of the present invention does not produce the same results.

Further, when the process of the present invention was used in conjunction with the shorter reaction time according to Pelzer, the resulting product still contained discoloring impurities. HR 144-3 was produced using the process of the present invention, but used the shorter reaction time of Pelzer. As is clearly shown in Tables 2 and 3 of the Declaration, HR 144-3 showed the presence of discoloring byproducts of phenylene-bis-benzimidazole-tetrasulfonic acid disodium salt that the present invention (HR 285) overcomes (compare HR 144-3 to HR 285). The cosmetic formulation containing HR 144-3 displayed "faintly pink, slightly pink, slightly pink and pink" discoloration properties, respectively. In contrast, the cosmetic formulation containing the product of the present invention, HR 285, remained free of color.

Thus, even when the process of the present invention was used with the shorter reaction time of Pelzer, the resulting product still contained discoloring byproducts. This demonstrates the difficulty that the Applicants had to overcome in order to prevent the phenylene-bis-benzimidazole-tetrasulfonic acid disodium salt from containing discoloring byproducts. The experiments in the Declaration clearly show that routine experimentation with time and temperature would not have led one skilled in the art to the process of the present invention.

Paragraph 9c.

It is also the position of the Examiner that the record allegedly did not contain any disclosure by which the Examiner could asses the differences in kind between Pelzer and the present invention.

In response, Applicants respectfully request the Examiner to take into consideration the information contained in the Declaration and the visual evidence contained in Attachment A. The comparative data contained therein clearly demonstrates that the process of the present invention produces phenylene-bis-benzimidazole-tetrasulfonic acid disodium salt that is free of discoloring impurities. Thus, the results are not merely different in **amount**, they are different in **kind**. In contrast to the present invention, Pelzer does not teach how to remove **discoloring byproducts**.

Paragraph 9d.

Finally, it is the position of the Examiner that Wang and Heywang are cited for their generic teachings for aspects of processes involving sulfonates and sulfonic acids.

Applicants respectfully traverse the rejection. Applicants respectfully submit that the present invention is not obvious over the primary reference, and that the secondary references do not remedy the defects of the primary reference. Further, neither Wang nor Heywang teach the reduction in discoloring by-

products according to Claim 3. Also, as stated above, the unexpected result is that the modified process removes discoloring components in spite of an increase in impurities. Applicants respectfully request that the rejection based on Wang and Heywang be removed.

In conclusion, it is the unique combination of steps in Claim 3 that ensures that the discoloring components are removed from the tetrasulfonate product in a way that is sufficient to avoid discoloration of formulations. This difference is property is not obvious over the teaching of the prior art. Applicants respectfully request that the rejections based on these prior art references be removed.

Favorable consideration and early issuance of the Notice of Allowance are respectfully requested. Should further issues remain prior to allowance, the Examiner is respectfully requested to contact the undersigned at the indicated telephone number.

Respectfully submitted,

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Dated: **November 17, 2003**

CERTIFICATE OF MAILING AND AUTHORIZATION TO CHARGE

I hereby certify that the foregoing AMENDMENT C for U.S. Application No. 09/995,328 filed November 27, 2001, was deposited in first class U.S. mail, postage prepaid, addressed: Mail Stop:_____; Commissioner for Patents, P.O. Box 1450; Alexandria, VA 22313-1450, on **November 17, 2003.**

The Commissioner is hereby authorized to charge any additional fees which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.

Carrie L. Bootcheck

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ATTACHMENT A